REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the remarks which follow.

I. Disposition of Claims

Claim 46, 48, 51, and 53-60 are pending in this application.

II. Rejections under 35 U.S.C. §102

A. Chen *et al.* (U.S. Patent No. 5,558,879)

Claims 46, 48, 51, 53-58, and 60 were rejected under 35 U.S.C. §102(b) as being anticipated by Chen *et al.* Reconsideration of this rejection is respectfully requested.

Claim 46 recites a dosage form comprising (1) an osmotic core comprising a therapeutic agent, (2) a first membrane in contact with said formulation, the first membrane comprising a hydrophobic substance and a hydrophilic substance, the hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of said osmotic core, (3) a second membrane comprising a semipermeable composition positioned over an outside surface of said first membrane, wherein the second membrane maintains its physical and chemical integrity as the dosage form dispenses the therapeutic agent, and (4) at least one passageway formed across the membranes for dispensing the therapeutic agent from the dosage form.

The Chen et al. patent discloses a dosage form comprising (a) a compressed core containing a medicament, (b) a first inner coating layer for sustained release of the medicament comprising a plasticized water insoluble pharmaceutically acceptable polymer and a pharmaceutically acceptable water soluble polymer, and (c) a second outer coating layer for immediate release of a medicament comprising a medicament and a water soluble polymer.

The Chen et al. patent does not disclose or teach that the second outer coating layer comprises a semipermeable composition as recited in claim 46 of the instant application. A semipermeable composition is permeable to aqueous fluid in the gastrointestinal tract but impermeable to passage of drug. The water-soluble binders disclosed in the Chen et al. patent are not semi-permeable compositions. Because the Chen et al. patent does not disclose or teach

that the second outer coating layer may include a semipermeable composition, the Chen et al. patent cannot anticipate claim 46. Withdrawal of the anticipation rejection of claim 46 over the Chen et al. patent is respectfully requested. Claims 48, 51, and 53-58, being dependent from claim 46, are likewise patentable over the Chen et al. patent. Claim 60, which recites a method of delivering a therapeutic agent to a subject comprising administering the dosage form of claim 46, is also patentable in view of the foregoing arguments.

B. Bartoo *et al.* (U.S. Patent No. 4,743,248)

Claims 46, 48, 51, and 53-60 were rejected under 35 U.S.C. §102(b) as being anticipated by Bartoo *et al.* Reconsideration of this rejection is respectfully requested.

Claim 46 recites a dosage form comprising (1) a formulation comprising a therapeutic agent, (2) a first membrane in contact with said formulation, the first membrane comprising a hydrophobic substance and a hydrophilic substance, the hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of said formulation, (3) a second membrane comprising a semipermeable composition positioned over an outside surface of said first membrane, wherein the second membrane maintains its physical and chemical integrity as the dosage form dispenses the therapeutic agent, and (4) at least one passageway formed across the membranes for dispensing the therapeutic agent from the dosage form.

The Bartoo et al. patent discloses a dosage comprising (a) an internal compartment comprising a beneficial agent, (b) an inner wall surrounding the compartment, the inside wall comprising a polymeric formulation that is sensitive to changes in pH, and (c) an outer wall comprising a semipermeable polymer. The inner wall is described in detail in column 4, lines 6-46 of the patent. The Bartoo et al. patent teaches that representative materials for forming the inner wall are those that dissolve on exposure to alkaline solution.

While the polymeric formulation of the inner wall of the Bartoo et al. patent may include a hydrophobic substance and hydrophilic substance, the Bartoo et al. patent does not disclose or teach that such hydrophilic substance exhibits an aqueous solubility that is responsive to osmotic pressure and/or ionic strength of the formulation in the internal compartment. The Examiner states that the Bartoo et al. patent discloses polyethylene glycol (PEG), which is a hydrophilic substance. The Examiner, however, failed to demonstrate that PEG or any other component

included in the inner wall of the Bartoo et al. patent exhibits an aqueous solubility responsive to osmotic pressure and/or ionic strength of the formulation in the internal compartment.

The Examiner should note that the specification of the instant application lists PEG as a material that could be included in the first membrane but does not certify that PEG is a hydrophilic substance that exhibits an aqueous solubility responsive to osmotic pressure and/or ionic strength. The Examiner should further note that not all hydrophilic substances exhibit an aqueous solubility that is responsive to osmotic pressure and/or ionic strength. This is demonstrated, for example, by Example 1 and FIG. 5 of the instant application, where dissolution rates of different molecular weights of a hydrophilic material, KLUCEF EF, GF, and HF, are compared. The instant application provides a test for screening hydrophilic materials exhibiting the properties recited in claim 46.

Because the Bartoo et al. patent does not disclose or teach a first membrane as recited in claim 46, the Bartoo et al. patent cannot anticipate claim 46. Withdrawal of the rejection of claim 46 over the Bartoo et al. patent is respectfully requested. Claims 48, 51, and 53-59, which depend from claim 46, are likewise patentable over the Bartoo et al. patent. Claim 60, which recites a method of delivering a therapeutic agent to a subject comprising administering the dosage form of claim 46, is also patentable in view of the foregoing arguments.

III. Conclusion

The rejected claims have been amended and/or shown to be allowable over the prior art. Applicant believes that this paper is fully responsive to the Office Action dated July 14, 2005, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC 2762C1).

Respectfully submitted,

Date: 1/5/06

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